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Remarks

Claim Rejections - 35 USC § 103

In paragraph 1 of the Office action mailed April 9, 2004, claims 1, 2, 6, 9-12, 19, 21, 22 and 26 were rejected under 35 U.S.C. 103(a) as unpatentable (obvious) over Ishikawa et al. (US 6464687) in view of Ben-Haim et al (US 6571127). Applicants respectfully traverse this rejection and requests reconsideration in light of the remarks below.

The pending independent claims (claims 1 and 21) cover implanting a device to apply electrical stimulation to keep or direct delivered medications to a certain location within the body via hypoperfusion ("decreased blood flow through organs or tissue") or hyperperfusion ("increased blood flow"), respectively. As explained further below, a person of ordinary skill in the art would not have been motivated by Ishikawa et al. and Ben-Haim et al, even in combination with the other cited art, to implant a device to apply electrical stimulation to cause hypoperfusion or hyperperfusion to keep or direct drugs to a certain location within the body. These references fail to teach the claimed subject matter as a whole, as 35 U.S.C. 103 requires.

More specifically, independent claim 1 covers implanting a device to apply electrical stimulation in a first area of a patient in order to modulate circulatory perfusion in a second area that is targeted for medication delivery, and modifying the electrical stimulation to cause *hypoperfusion to restrict perfusion of the medication* in the second area. Independent claim 21 covers implanting a device to apply electrical stimulation in a first area of a patient in order to modulate circulatory perfusion in a second area that is targeted for to receive medication delivered to a third area, and modifying the electrical stimulation to cause *hyperperfusion to focus the medication* in the second area.

Ishikawa et al. teach that their device "provides an actuator function to stimulate the tissues into which drugs are to be released" (col. 29 @ 35-36) and that "[a] remote control...

may be implanted in the body proximate to or remoted [sic] from the ball 110" (col. 7 @ 7-10). However, there is no discussion of what type of stimulation should be used or why, and certainly no suggestion that the stimulation should be used to cause hypoperfusion or hyperperfusion to keep or direct the drugs to a certain location within the body.

As the Examiner points out, Ishikawa et al. do not disclose "the method seeking to cause hypoperfusion/hyperperfusion." Applicants submit that Ishikawa et al. therefore *cannot* disclose that "perfusion of [a] medication is restricted due to the hypoperfusion" (claim 1) or that "medication is focused into [an] area of the patient due to the hyperperfusion" (claim 21).

In the paragraph spanning pages 2 and 3, the rejection states:

> Ben-Haim et al. teach tissue treatment using electrical stimulation and drugs for the purpose of changing profusion to hypoperfusion and hyperperfusion states. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used electrical stimulation and drugs to change tissue profusion between hypoperfusion and hyperperfusion states in the Ishikawa et al. system in order to reduce the strain on the cardiac tissue and optimize the efficacy of the treatment for the patient (col. 5 @ 17-29; col. 15 @ 39-47).

Even if Ben-Haim et al. taught "electrical stimulation and drugs to change tissue profusion between hypoperfusion and hyperperfusion" this falls short of using stimulation-induced hypo- and hyperperfusion *to restrict or focus medication* to targeted tissue, as covered by independent claims 1 and 21. While Ben-Haim et al. mention that "[e]lectrically induced relaxation of blood vessels may be used instead of or in addition to pharmaceuticals" (col. 5 @ 19-21), this does not teach or suggest stimulus-induced hypoperfusion where "medication is restricted due to the hypoperfusion" or hyperperfusion where "medication is focused...due to the hyperperfusion." Ben-Haim et al. also mention "reducing the preload and/or the afterload on the heart [to] allow better perfusion of the ischemic tissues" (col. 5 @ 24-29). This also fails to teach or suggest stimulation-induced hypo- or hyperperfusion *to restrict or focus medication* as claimed in independent claims 1 and 21, respectively.

Ben-Haim et al. note that "various embodiments of the present invention...can be used in conjunction with drug therapies, with a synergistic interaction and/or to allow a reduced dose of drug to produce a desired effect and/or to allow increased dosages of drugs to be used, while limiting their adverse side effects using electrical control" (col 15 @ 39-45). Yet, there is no discussion or suggestion of *stimulation to create hypo- or hyperperfusion to keep or direct drugs to a certain location within the body*. There is no suggestion that the "desired effect" is to keep or direct drugs to a certain location within the body, and no suggestion that the "electrical control" of "adverse side effects" is achieved via hypoperfusion or hyperperfusion *to keep or direct the drugs to a certain location* within the body.

As Ben-Haim et al. and Ishikawa et al. fail to teach stimulation-induced hypo- and hyperperfusion to restrict or focus medication, these references fall short of meeting or suggesting all elements of independent claims 1 and 21. Based on the above remarks, reconsideration of the rejection of these claims is respectfully requested.

In the first paragraph of the Office action mailed April 9, 2004, **claims 2, 6, 9-12, 19, 22 and 26** were also rejected as unpatentable (obvious) over Ishikawa et al. in view of Ben-Haim et al. Claims 2, 9, 11 and 12 depend from independent claim 1, so should be allowable for the same reasons given above in support of independent claim 1. Claims 6, 10, 19, 22 and 26 depend from independent claim 21, so should be allowable for the same reasons given above in support of independent claim 21. Acknowledgment of the same is earnestly solicited.

In paragraph 2 of the Office action mailed April 9, 2004, **claims 3, 4, 27 and 28** were rejected under 35 U.S.C. 103(a) as unpatentable over Ishikawa et al (US6464687) in view of Ben-Haim et al (US 6571127) and further in view of Garfield et al (US6356777). Claims 3 and 4

depend from independent claim 1, so should be allowable for the same reasons given above in support of independent claim 1. Claims 27 and 28 depend from independent claim 21, so should be allowable for the same reasons given above in support of independent claim 21.

In paragraph 3 of the Office action, **claims 5 and 25** were rejected under 35 U.S.C. 103(a) as unpatentable over Ishikawa et al (US6464687) in view of Ben-Haim et al (US 6571127) and further in view of Hobbs et al (US5916154). Claim 5 depends from independent claim 1, so should be allowable for the same reasons given above in support of independent claim 1. Claim 25 depends from independent claim 21, so should be allowable for the same reasons given above in support of independent claim 21.

In paragraph 4 of the Office action, **claims 23 and 24** were rejected under 35 U.S.C. 103(a) as unpatentable over Ishikawa et al (US6464687) in view of Ben-Haim et al (US 6571127) and further in view of Kieval et al (US6073048). Claims 23 and 24 depend from independent claim 21, so should be allowable for the same reasons given above in support of independent claim 21.

Conclusion

In summary, applicants' representative has carefully read Ishikawa et al. and Ben-Haim et al., and respectfully submits that these patents, even in combination with the other cited art, do not show "applying [a] stimulus...to modulate circulatory perfusion in [an] area of the patient...targeted to receive medication...to cause hypoperfusion...wherein perfusion of the medication is restricted due to the hypoperfusion" or "to cause hyperperfusion...wherein the medication is focused...due to the hyperperfusion". As all pending claims depend directly or indirectly from independent claim 1 or 21, applicants respectfully request consideration of independent claims 1 and 21, and their dependent claims, in light of these remarks.

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In view of the foregoing, it is respectfully submitted that the rejections have been overcome and that the pending claims are in condition for allowance. An indication of allowability of all pending claims, claims 1-6, 9-12, 19 and 21-28, is earnestly solicited.

The Examiner is invited to telephone the undersigned, Laura Bishop, at her convenience should any issues remain after consideration and entry of this response, in order to permit early resolution of the same.

Respectfully Submitted,

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Date

Laura Haburay Bishop
Reg. No. 47,424

Please direct all written inquiries to:
Bryant R. Gold
Advanced Bionics Corporation
12740 San Fernando Road
Sylmar, CA 91342

Please direct all telephone inquiries to:
Laura Haburay Bishop
Telephone: (661) 362-1906
Fax: (661) 362-1507